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(Previously 0-03-046)

REMARKS

Claim Amendments

The Applicant herein amends claims 9, 10, 11, 12 and 15 in order to expressly claim an order of process steps. It is now expressly claimed that the pre-treatment or post-treatment steps occur before or after the gaseous nitric oxide exposure step, respectively. Additionally, claim 22 is amended for further clarification.

Rejections over Stenzler (U.S. Patent No. 6,432,077)

The Office Action has rejected claims 9-15 and 17-26 under 35 U.S.C. § 103(a) as being unpatentable over Stenzler (U.S. Patent No. 6,432,077). It is respectfully maintained that the Office Action has not established a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, in the references themselves to modify the reference or to combine reference teachings to arrive at all the claim limitations. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See MPEP § 2142. The Office Action has not shown that the *single* cited reference teaches or suggests each and every limitation of the claims.¹

¹ "Obviousness can only be established by ... modifying the teachings of the prior art to produce the claimed invention where there is some teaching suggestion, or motivation to do so found either explicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." MPEP § 2143.01. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *Id.* See also; *In re Kotzab*, 217 F.3d 1365, 1370, 55 U.S.P.Q.2d 1313, 1316-7 (Fed. Cir. 2000) ("Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference."); *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990) (holding that although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the references to do so."); *Ex Parte Gerlach*, 212 U.S.P.Q. 471 (Bd. Pat. Int. 1980) ("There is nothing in the statutes

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The Office Action states, without any support, that "Stenzler's method does disclose a step wherein the wound is pretreated or posttreated with nitric oxide gas plus an agent." The Office Action similarly states, without any support, that "Stenzler teaches that the application of gaseous nitric oxide plus agent is prior to or after exposing the wound to nitric oxide" The Office Action, however, cannot provide any citation in the Stenzler Patent to support its statements and rejection of claims 9-15, 17-26.

The Office Action has not shown how these statements are supported even when the Office Action's equating of "oxygen" as a "wound healing agent" is considered. (Office Action at 2). It should be noted that the claims 9, 11-12, 15, 17-26 do not simply recite exposure to nitric oxide gas, but recites specific order of steps not found in the prior art of record. Moreover, it is respectfully submitted that the Office Action's rejection is equally flawed because there is no evidence provided to support the conclusory statement that "oxygen" is a "wound healing agent" (Office Action at 2). Neither is there any discussion of how supposedly the combination of "oxygen" and "nitric oxide gas" are administered before or after the exposure to "an effective amount of gaseous nitric oxide for a period of time that exceeds eight consecutive hours," as required, for example, by claims 9 and 11-12. There is equally no discussion in the Office Action of how the cited reference purportedly teach "pretreating ... with a wound healing agent other than nitric oxide gas" "prior to the exposing step" to "an effective amount of gaseous nitric oxide," as recited in claim 15. Thus, the Office Action fails to establish a *prima facie* case of obviousness.

Additionally, the Office Action does not even discuss, for example, the step of "wetting, dampening, or moistening the damaged tissue following the gaseous nitric oxide exposing step," as

or the case law which makes "that which is within the capabilities of one skilled in the art" synonymous with obviousness.")

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recited in claim 10; the step of "administering exogenous nitric oxide to *tissue flap* and surrounding damaged area in order to promote *flap viability* and increase local blood flow to *donated tissue*," as recited in claim 13;² nor the type of impermeable wound cover that is recited in claim 17 ("transparent and allows for permeation of small molecules, while simultaneously preventing microbial contamination of the damaged tissue from a source outside of the wound cover.") Thus, it is respectfully submitted that the rejection of these claims are equally improper.

The Office Action is deficient in establishing a *prima facie* case of obviousness, for an additional reason, because it fails to show any motivation or suggestion to modify the cited reference to satisfy the claims under an obviousness analysis. The Office Action has not pointed to any teaching or suggestion for satisfying each of the claimed limitations in the above discussed claims.

With respect to claim 14, the Office Action states only in a conclusory fashion that "nitric oxide is applied from a pressurized cylinder [in the Stenzler patent] which suggests a spray application method." Office Action at 2. The leap in the Office Action's analysis is not understood, and it fails because no supporting evidence for this conclusory statement is provided. The Office Action has not provided any evidence that a "pressurized cylinder" necessarily indicates a "spray application method" as opposed to a gas flow application method utilizing, for example, tubings, flow meters, and pressure regulating valves. An examiner's own conclusory statement without any evidentiary support is insufficient to establish a *prima facie* case of obviousness or support a finding of motivation or suggestion, as required by the Federal Circuit.³

² Claim 13 finds support, for example, on Page 19 of the Specification, wherein a donated tissue flap is treated with nitric oxide gas. The Office Action does not point to anything to show how this element is satisfied in the prior art.

³ See *In re Lee*, 227 F.3d 1338, 1342-45, 61 USPQ2d 1430, 1433-35 (Fed. Cir. 2002); *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (a broad conclusory statement regarding the obviousness of modifying a reference, standing alone, is not evidence).

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The Federal Circuit has repeatedly cautioned against the use of hindsight in rejecting claims under 35 U.S.C. 103.⁴ The Office Action has improperly used hindsight because all these teachings, as claimed, come from Applicant's disclosure alone. "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure." MPEP § 2143. For at least this additional reason, it is respectfully submitted that the Office Action has failed to establish a *prima facie* case of obviousness.

Thus, Applicants respectfully submit that the rejection of claims 9-15 and 17-26 be withdrawn and a Notice of Allowance be issued for these claims.⁵

Rejections over Hole et al (U.S. Publication No. 2002/0138051)

The Office Action has rejected claims 9-15 and 17-26 under 35 U.S.C. § 103(a) as being unpatentable over Hole et al (U.S. Publication No. 2002/0138051). It is respectfully maintained that the Office Action failed to establish a *prima facie* case of obviousness. The Office Action has not shown that the reference teaches or suggests each and every limitation of the claims.

The Office Action's statements for the rejection of these claims based on Hole is substantially the same as the conclusory statements made using the Stenzler Patent. Thus, the rejection should fail for all the same reasons discussed above. No support is provided by the Office Action for the conclusory statements made in the rejection for limitations expressly recited in the

⁴ McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351 (Fed. Cir. 2001) (explaining that to reach a proper determination under 35 U.S.C. 103, knowledge of applicant's disclosure must be put aside in reaching this determination); see also, MPEP § 2142 ("The tendency to resort to 'hindsight' based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.").

⁵ Applicant notes that the Patent Office has previously found these claims to be allowable in the prior office action and respectfully submits that the new Office Action has raised no valid basis for rejecting these claims.

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claims. The Office Action is similarly silent with respect to a number of these claimed limitations, and provide only conclusory and unsupported statements regarding any motivation to combine or modify. Thus, for all the reasons discussed above, Applicant respectfully submits that the rejection of claims 9-15, 17-26 as being unpatentable over Hole is improper and respectfully requests the withdrawal of this rejection.

CONCLUSION

For the foregoing reasons, Applicant believes that the pending claims, claims 9-15 and 17-26 of this application are patentable and respectfully requests the issuance of a Notice of Allowance.

If the undersigned can be of any assistance to the Patent Office, a telephone call is respectfully requested. If any fees are required by this filing, the Commissioner is authorized to charge Sidley Austin Brown and Wood's Deposit Account # 50-1597.

Respectfully Submitted

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Date:

8/8/05

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